

1 MEDICAL PATIENT FLUID MANAGEMENT
2 INTERFACE SYSTEM AND METHOD
3

4 **Cross-Referenced to Related Disclosure Documents**
5

6 This application relates to Disclosure Document Nos. 414,622 for VAC® System
7 Applications; Wound Dressings, filed February 18, 1997; and No. 415,021 for Concepts For
8 Use of Biodegradable Beads and Vacuum Bag In VAC® System Applications; Wound
9 Dressings, filed February 28, 1997, which are incorporated herein by reference.
10

11 **Background of the Invention**
12

13 **I. Field of the Invention.**

14 The present invention relates generally to patient interfaces for fluid management in
15 medical care, and in particular to a system for interfacing a vacuum-assisted fluid
16 extraction/supply system with a patient.
17

18 **II. Description of Related Art**

19 Fluid management significantly affects many aspects of health care and is involved in
20 many medical procedures. For example, wound care typically involves absorbing and/or
21 draining blood, serum and other body fluids from the patient. Various surgical procedures
22 also require fluid drainage. For example, skin grafts have fluid drainage that needs to be
23 managed at both the donor and graft sites.

1 Various types of porous, absorbent dressing materials have been used for dressing
2 wounds to accumulate body fluids. The dressing materials facilitate drainage and also
3 collection and disposal of the fluids. A disadvantage with many conventional dressings is
4 that they require changing to reduce risks of infection and to maintain effectiveness.
5 However, dressing changes can add significantly to treatment costs and are associated with
6 patient discomfort and medical risks such as infection and damage to reepithelialized tissue.
7 Accordingly, vacuum sources have been employed to drain wounds. For example,
8 Zamierowski U.S. Patents No. 4,969,880; No. 5,100,396; No. 5,261,893; and No. 5,527,293
9 pertain to wound dressings, fluid connections, fastening systems and medical procedures
10 utilizing same in connection with vacuum-assisted wound drainage, and are incorporated
11 herein by reference.

12 A wound drainage device using a hand-operated suction bulb is shown in the George,
13 et al. U.S. Patent No. 4,392,858. Motorized suction pumps can be employed to provide
14 consistent, sub-atmospheric vacuum pressure for maintaining an effective drainage flow. The
15 Richmond et al. U.S. Patents No. 4,655,754 and No. 4,826,494 disclose vacuum wound
16 drainage systems which can be connected to motorized vacuum pumps.

17 Another important objective in designing an effective wound drainage system is to
18 provide an effective interface with the patient. Ideally the patient interface should
19 accommodate various types of wounds in different stages of recovery for as broad a range of
20 applications as possible. Promoting optimum wound healing typically involves maintaining
21 the right moisture level to avoid overdrying without causing the wound to macerate from
22 excessive moisture. Pressures should be sufficient for effective drainage without creating
23 significant negative forces, which could cause pressure necrosis or separate freshly-applied
24 skin grafts.

1 Wound treatment procedures can also include infusing wound sites with liquids to
2 flush contaminants, counter infection, promote healing growth and anesthetize the wound.
3 Prior art fluid delivery systems include a device for treating tissues disclosed in the Svedman
4 U.S. Patent No. 4,382,441; a product and process for establishing a sterile area of skin
5 disclosed in the Groves U.S. Patent No. 3,367,332; and the transdermal infusion device
6 disclosed in the Westin U.S. Patent No. 4,605,399. Equipment has also been available which
7 flushes and collects contaminants from wounds.

8 Heretofore, there has not been available a patient interface system and method with
9 the advantages and features of the present invention.

10
11 **Summary of the Invention**
12

13 In the practice of the present invention, a patient interface system is provided which
14 includes a fluid transfer subsystem with a primary transfer element and a secondary transfer
15 element/manifold. An interface drape subsystem includes first and second drapes for
16 covering the first and second fluid transfer elements respectively. A fluid conveyance
17 subsystem includes a vacuum source connected to the secondary fluid transfer
18 element/manifold by a suction tube and a fluid source connected to the primary fluid transfer
19 element by a tubing system. In the practice of the method of the present invention, a method
20 of interfacing fluid management equipment with a medical patient includes the steps of sizing
21 and placing a primary fluid transfer element, draping the primary fluid transfer element with a
22 primary drape, cutting an outlet opening in the primary drape, inserting a suction tube in a
23 secondary fluid transfer element/manifold, placing the secondary fluid transfer
24 element/manifold over the drape outlet opening; draping the secondary fluid transfer

1 element/manifold; applying a sub-atmospheric, negative vacuum source to the primary
2 transfer element via the suction tube and the secondary fluid transfer element/manifold; and
3 connecting a fluid supply to the primary transfer element via an inlet tubing subassembly.
4

5 Objects and Advantages of the Invention

6

7 The principal objects and advantages of the present invention include: providing a
8 patient interface system for interfacing a vacuum source with a patient wound site; providing
9 such a system which interfaces a fluid source with a patient; providing such a system which
10 can be used to uniformly distribute a vacuum force over a wound site; providing such a
11 system which can minimize interference from clogging caused by matter in fluid being
12 drained; providing such a system which is adapted to introduce fluids to a wound site;
13 providing such a system which can reduce the frequency of dressing changes in connection
14 with treating a wound; providing such a system which can provide for the effective control of
15 various operating parameters in wound treatment with a hydrophobic foam rubber sponge
16 material; providing such a system which is particularly designed for use with automated
17 vacuum drainage equipment; providing such a system which can promote significantly faster
18 healing; and providing such a system which is economical to manufacture, efficient in
19 operation and particularly well-adapted for the proposed usage thereof.

20 Other objects and advantages of this invention will become apparent from the
21 following description taken in conjunction with the accompanying drawings wherein are set
22 forth, by way of illustration and example, certain embodiments of this invention.

23 The drawings constitute a part of this specification and include exemplary
24 embodiments of the present invention and illustrate various objects and features thereof.

369020-6T46F060

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18

Brief Description of the Drawings

Fig. 1 is an exploded, perspective view of a patient interface system embodying the present invention.

Fig. 2 is a fragmentary perspective view of the patient interface system, particularly showing the application of a primary fluid transfer element and a primary drape thereof.

Fig. 3 is a perspective view of an assembled patient interface system embodying the present invention.

Fig. 4a is a schematic diagram of a prior art patient interface system.

Fig. 4b is a schematic diagram of the patient interface system embodying the present invention.

Fig. 5 is a flow chart showing the steps of the method of the present invention.

Fig. 6 is a schematic diagram of a patient interface system comprising a first modified embodiment of the present invention.

Fig. 7 is a schematic diagram of a patient interface system comprising a second modified embodiment of the present invention.

1 Detailed Description of the Preferred Embodiments

2
3 **I. Introduction and Environment.**

4 As required, detailed embodiments of the present invention are disclosed herein;
5 however, it is to be understood that the disclosed embodiments are merely exemplary of the
6 invention, which may be embodied in various forms. Therefore, specific structural and
7 functional details disclosed herein are not to be interpreted as limiting, but merely as a basis
8 for the claims and as a representative basis for teaching one skilled in the art to variously
9 employ the present invention in virtually any appropriately detailed structure.

10 Referring to the drawings in more detail, the reference numeral 2 generally designates
11 a patient interface system embodying the present invention. The interface system 2 generally
12 comprises a fluid transfer subsystem 4, an interface drape subsystem 6, and a fluid
13 conveyance subsystem 8.

14
15 **II. Fluid Transfer Subsystem 4.**

16 The fluid transfer subsystem 4 includes a primary fluid transfer element 12 which can
17 comprise, for example, a suitable open-cell, porous foam material (e.g., polyurethane ^{ester} ~~ether~~).
18 The degree of hydrophobic versus hydrophilic properties of the material comprising the
19 element 12 can be determined by the particular application of the interface system 2. For
20 wound drainage and for the introduction of various liquid medications and treatments, a
21 large-cell, hydrophobic material is preferred. For example, hydrophobic polyurethane ether
22 has been found to be a suitable material for many applications. Likewise, polyvinyl acetate
23 (PVA) or small-cell, hydrophilic polyurethane foam can be used for its hydrophilic properties
24 where such are desired. The primary fluid transfer element 12 includes a bottom or contact

1 surface 12a, a top surface 12b, a perimeter 12c and an interior portion 12d of the top surface
2 12b.

3 A secondary fluid transfer element/manifold 14 also preferably comprises a suitable
4 foam material and includes a bottom or contact surface 14a, a top surface 14b, a perimeter
5 14c and an interior portion 14d. A pair of secondary fluid transfer elements/manifolds 14.1
6 and 14.2 can be provided for handling evacuation and supply respectively as shown in Fig.
7 4b, and each can be connected to the primarily fluid transfer element 12 in the manner
8 described.

069020-6T46T060

069020" 6TH 15T 060

1 **III. Interface Drape Subsystem 6.**

2 An interface drape subsystem 6 is provided for draping or covering the fluid transfer
3 subsystem 4 and the areas surrounding same on a patient 16. The drape subsystem 6 includes
4 a primary drape 18 placed over the primary fluid transfer element 12 and extending beyond its
5 perimeter 12c. The drape 18 can have one or more openings formed therein, such as the inlet
6 and outlet openings shown at 20a,b for respectively admitting fluid to and extracting fluid
7 from the primary transfer element 12. Additional drape subsystem components can include
8 an inlet access drape 22 and an outlet access drape 24, the latter covering the secondary fluid
9 transfer element/manifold 14 in the example shown.

10 The drapes 18, 22, 24 can comprise any suitable material, although a semi-permeable
11 membrane is often preferred for facilitating wound healing by selectively admitting air while
12 retaining liquids and minimizing the risk of infection by excluding contaminants. An
13 example of such a material is marketed under the trademark "TEGADERM®" by the
14 Minnesota Mining and Manufacturing Company (3M) of St. Paul, Minnesota. Other semi-
15 permeable materials are available and can be successfully employed with the present
16 invention. The drapes 18, 22, 24 preferably comprise a film material with a contact adhesive
17 on one side thereof to facilitate adhering the drapes 18, 22, 24 to the patient 16 around a
18 wound site 17, to the fluid transfer elements 12, 14 and to other components of the patient
19 interface system 2. However, a non-adhesive material can be used for retention in place by
20 vacuum pressure (i.e., negative, sub-atmospheric pressure) within the closed system in
21 combination with positive atmospheric pressure acting externally on the closed interface
22 system 2. Still further, one or more of the drapes 18, 22, 24 could be sized such that it could
23 be wrapped around a patient and held in place by a suitable securing action. One or more of
24 the drapes 18, 22, 24 could be applied as a single patch panel; as a face-to-face pair of

9

1 opposing panels; or as a folded sheet and, furthermore, could comprise an impervious,
2 impermeable material with suitable inlet and outlet openings, such as those shown at 22, 24,
3 to admit and extract various combinations of fluids.

4

5 **IV. Fluid Conveyance Subsystem 8.**

6 The fluid conveyance subsystem 8 functions to extract fluids, including the patient's
7 blood, serum, etc., from the interface system 2, and also to introduce various fluids, such as
8 antibiotics, analgesics and growth factors into the interface system 2. A vacuum source
9 26 can comprise, for example, a vacuum assisted closure "VAC®" system available from
10 Kinetic Concepts, Inc. of San Antonio, Texas. The "VAC®" system provides a motorized
11 pump, a fluid collection receptacle, variable pressure control, variable timing and automatic
12 safety shut-down features in a single, portable unit which can be pre-programmed to apply
13 suction either intermittently for a pulsatile effect with predetermined frequency, amplitude
14 and duration of the sub-atmospheric pressure gradient or continuously in a constant pressure
15 mode of operation.

16 A suction tube 28 includes a proximate end 28a embedded in the secondary fluid
17 transfer element/manifold 14 and a distal end 28b connected to the vacuum source 26. The
18 suction tube proximate end 28a can be provided with multiple orifices 28c to facilitate
19 distribution of the suction force throughout the secondary transfer element/manifold 14.

20 A primary fluid source 30 can comprise, for example, a suitable container and can be
21 connected to the primary fluid transfer element 12 by an inlet tubing subassembly 32 which
22 can comprise, for example, the type commonly used for intravenous applications with tubing
23 34, suitable leur lock connectors 36 and a catheter 38 for interfacing same with the primary
24 fluid transfer element 12. A secondary fluid source 40 can supplement the primary fluid

1 source 30 to achieve a desired flow of fluid, medication, growth factor, etc. into the patient
2 interface system 2.

3 A fluid conveyance control system 42 includes a suitable microprocessor 42a and is
4 connected to the vacuum source 26. The controller 42 controls pressures, flow rates, timing
5 sequences of intermittent vacuum, and includes control features which permit the shut-down
6 of the system 2 or its automated use. The controller 42 can comprise, for example, the
7 control features in a VAC® vacuum-assisted closure system and its on-board computer can
8 comprise the controller microprocessor 42a.

9 The connections of the suction tube 28 and the inlet tubing subassembly 32 with the
10 primary and secondary fluid transfer elements 12, 14 can be suitably covered by the inlet and
11 outlet access drapes 22, 24. Moreover, the secondary fluid transfer element/manifold 14 is
12 preferably placed over the outlet opening 20b formed in the primary drape 18. With the
13 addition of the secondary drapes 22, 24, the fluid conveyance subsystem 8 is fluidically
14 connected to the fluid transfer subsystem 4.

15

16 **V. Operation.**

17 The patient interface system 2 is adaptable for use in connection with various medical
18 procedures responsive to particular patient conditions. For example, wound drainage can be
19 accomplished by applying the primary fluid transfer element 12, which can be cut (e.g., at cut
20 lines 25) to an appropriate size and configuration for a particular wound, covering it with a
21 primary drape 18 and forming an outlet opening 20b therein. A secondary fluid transfer
22 element 14 functions as a manifold for communicating negative vacuum pressure to the
23 primary fluid transfer element 12 and is placed over the drape outlet opening 20b with an
24 outlet access drape 24 thereover. The outlet access drape 24 functions to retain the secondary

1 fluid transfer element/manifold 14 in its proper position on top of the primary transfer
2 element 12, and also facilitates directing fluids from the wound to the suction tube 28. The
3 controller 42 can be programmed to provide either continuous or intermittent suction via the
4 vacuum source 26 at suitable predetermined intervals and pressures. Multiple pressure
5 settings can be utilized, if necessary.

6 The hydrophobic, porous characteristics of the transfer elements 12, 14 facilitate
7 efficient passage of patient fluids therethrough, including various matter such as serum,
8 protein, blood, etc. Moreover, creating sub-atmospheric pressure (i.e., negative pressure)
9 within the closed environment of the interface system 2 can help control edema in the wound
10 area and in the surrounding tissues. The edema-counteracting effects of the interface system 2
11 can be varied by setting the controller 42 at different appropriate pressure settings and timing
12 sequences.

13 Liquid supply operations are accomplished by inserting the catheter 38 into the
14 primary transfer element 12. The connection can then be covered with an inlet access drape
15 22. Various other fluid-type connections can be utilized for introducing fluid (e.g., air,
16 nitrogen, oxygen, etc.) into the system 2. For example, an additional secondary transfer
17 element 14 for fluid supply purposes could be formed of a similar, porous, hydrophobic
18 material. The porous, hydrophobic characteristics of the primary transfer element 12
19 facilitate distribution of fluids introduced into the interface system 2 over the entire wound
20 area. Moreover, by controlling the vacuum sub-atmospheric pressures and timing, the fluids
21 introduced can be allowed to accumulate on the wound for absorption into the patient's
22 system. Thus, antibiotics and anesthetics can be effectively delivered for maximum benefit.
23 The wound can also be effectively flushed since the transfer elements 12, 14 act as efficient
24 conduits of liquids with continuous flow therethrough under operating conditions. The

12

090194-19-020599
069020-67457050

1 system 2 effectively differentiates gases and liquids in a controlled environment for
2 optimizing therapeutic benefits. Other fluid supply corrections include an injection port 33
3 connected to the tubing 34 and a vent 35 connected to the primary fluid transfer element 12.

4 The interface system 2 can be used for skin graft donor sites, which are often initially
5 covered with a material such as rayon gauze material 46. The drape 18 can comprise a
6 material such as TEGADERM® which is a vapor-permeable polyurethane film. Thrombin
7 can be introduced to the donor site. Drying of the donor site can be controlled by the
8 controller 42 operating the vacuum source 26, and also by introduction of other fluids. By
9 way of example, sub-atmospheric (vacuum) pressure in the range of approximately 75-125
10 millimeters of vacuum force on continuous operating mode for three days has been found to
11 promote effective skin graft donor site exudate control to a point at which the donor site can
12 be covered by a highly permeable material, such as "OPSITE 3000®" material. Such a highly
13 permeable material can maintain continued drying of the wound site 17 to promote epithelial
14 maturation without the application of additional sub-atmospheric (vacuum) pressure and with
15 little or no need for additional dressing changes. The rayon and the drape materials are both
16 relatively transparent and thus permit observation of the periwound area for monitoring the
17 patient's condition.

18 By way of example, the following steps would be involved in the treatment of a skin
19 graft donor site utilizing the interface system and method of the present invention:

20 1. Apply rayon 46 to the donor bed, with the optional topical application of
21 banked, unused skin graft therebelow and the optional application of thrombin.

22 2. Application of the primary fluid transfer element 12 directly on top of and just
23 overlapping the rayon 46.

1 3. Application of the primary drape 18 over the primary fluid transfer element 12,
2 with the drape 18 adhesively secured to the patients' surrounding, healthy skin.

3 4. Form a suitable outlet drape opening 20b and secure the secondary fluid
4 transfer element/manifold 14 (connected to the suction tube 28) over the drape outlet opening
5 20b. The outlet access drape 24 is then placed in covering relation over the secondary
6 transfer element/manifold 14, the suction tube 28 where it enters same and a portion of the
7 primary drape 18 around the outlet opening 20b.

869020" 6T46T060

14

1 5. Continuous suction by the vacuum source 26 at 75-125 millimeters vacuum
2 for approximately 72 hours.

3 6. Through a separate delivery site, either a catheter with a sealing injection port
4 fixed by placing a drape patch thereover, or by an injection with a needle and a drape film
5 adhesive patch sealing the injection site, liquid fluids can be instilled. For example, saline
6 can be instilled to flush blood film. Growth factors and/or antibiotics can be added. Just
7 before a dressing change, Xylocaine® local anesthetic can be instilled to control pain and can
8 be effectively, quickly and uniformly disbursed due to the hydrophobic nature of the primary
9 fluid transfer element 12.

10 7. Removal of the primary drape 18 and the primary fluid transfer element 12 to
11 expose the rayon dressing 46.

12 8. Application of a highly permeable polyurethane film layer 48 (e.g., OPSITE®
13 3000) in covering relation over the rayon dressing 46.

14 9. Monitor donor site for drying as a sign of reepithelialization and maturation
15 for about 2-3 weeks, whereupon spontaneous separation of the rayon dressing 46 or "OPSITE
16 3000®" film occurs.

17 Another application of the interface system 2 is for low-pressure (e.g., about 50
18 millimeters vacuum) for a predetermined time period of, for example, about one hour while
19 liquid is introduced through the fluid source 40. The lower pressure allows the liquid to
20 remain in the interface system 2 longer than it would at a higher vacuum pressure.

21

22 **VI. First Modified Embodiment Patient Interface System 102.**

23 Fig. 6 shows a patient interface system 102 comprising a first modified embodiment
24 of the present invention. The patient interface system 2 includes a modified fluid conveyance

1 subsystem 108 with a suction tube 128 forming an adjustable drop P-trap 130. The P-trap
2 130 includes a proximate section 132 with a proximate end 132a connected to either the
3 primary fluid transfer element 12 or the secondary fluid transfer element/manifold 14 and a P-
4 trap distal section 134 having a distal end 134a connected to the vacuum source 26. A female
5 telescoping portion 136 telescopically and vertically-adjustably receives a male telescoping
6 portion 138 of the P-trap distal section 134.

7 A fluid seal 140 is formed in the P-trap 130. The depth of the fluid seal 140 is
8 controlled by a telescopic interconnection 139 of the P-trap sections 132, 134. Thus, the
9 deeper the P-trap 130, the greater the pressure gradient across the suction tube 128 required to
10 draw gas through the suction tube 128. Under certain conditions of wound drainage, vacuum,
11 fluid seal 140 and P-trap 130 depth, gas bubbles intermittently pass through the suction tube
12 128 and create a pulsatile effect in the patient interface system 102. The amplitude, frequency
13 and duration of the pressure waves representing the pulse can be controlled by varying the
14 different operating parameters, including the depth of the P-trap 130 and the sub-atmospheric
15 vacuum force drawn by the vacuum source 26. A pulsatile effect approximately the pulse of
16 the patient 16 can be achieved. Such a pulsatile effect can have benefits in the treatment of
17 certain wounds, including the stimulation of cell growth and the stimulation of circulation to
18 the wound area 17.

19
20 **VII. Second Modified Embodiment Patient Interface System 202.**

21 Fig. 7 is a schematic diagram of a patient interface system 202 with a further modified
22 P-trap subassembly 230 including a tube shaper 232 comprising a back panel 234 and an
23 array of pins 236 projecting outwardly therefrom. The pins 236 are arranged in an array
24 comprising three columns with each column containing a number of rows. Different numbers

069020-6T4T060

1 and arrangements of pin arrays could also be employed. Different tube shaper configurations
2 could also be used. For example, various types of pins, knobs, clips, etc. can be used for
3 forming the downwardly-depending loops, such as that shown at 238, in the flexible tubing
4 32. As with the first modified embodiment patient interface system 102, a liquid seal 240 is
5 formed by the loops 238, and its resistance to the passage of gas through the exhaust tube 32
6 is determined by the depth of the loop 238, the viscosity of the liquid therein, the pressure
7 gradient across the P-trap subassembly 230, etc. The P-trap subassembly 230 can be formed
8 with the flexible suction tube 28, which can thus be continuous between either the primary or
9 the secondary transfer elements 12, 14 and the vacuum source 26.

10 It is to be understood that while certain forms of the present invention have been
11 illustrated and described herein, it is not to be limited to the specific forms or arrangement of
12 parts described and shown.

17